IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *State of Montana v. Purdue Pharma L.P., Case No. 1:18-OP-45604*	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

PURDUE'S OPPOSITION TO PLAINTIFF'S MOTION TO REMAND

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INTRODUCTION

Montana has affirmatively raised a substantial federal question sufficient to confer federal jurisdiction. It seeks a preliminary injunction that would require Purdue to give healthcare providers in Montana information about its prescription medications that is ***different*** from—and often ***inconsistent*** with—the information that the U.S. Food & Drug Administration (FDA) requires Purdue to communicate to doctors in Montana and every other state. Specifically, Montana's motion for a preliminary injunction demands that the court order Purdue to supplant the warnings and labeling that the FDA has determined to be scientifically accurate and sufficient with conflicting standards that the State posits are more appropriate based on its own idiosyncratic interpretation of a non-binding guideline from the Centers for Disease Control (CDC). The State's injunctive demands turn on uniquely federal legal principles and require the interpretation of controlling federal statutes and regulations—namely, the Food Drug and Cosmetic Act (FDCA) and the implementing regulations promulgated by the FDA. In such cases, "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable & Sons Metal Prods., Inc. v. Darhue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005).

Many courts have recognized that *Grable* jurisdiction arises where, as here, "the remedies [a party] seek[s] require nothing short of a reassessment, reevaluation and revamping of [a federal agency's earlier determination]" because that is "tantamount to asking the Court to second guess the validity of [a federal agency's] decision." *McKay v. City & Cty. of San Francisco*, 2016 WL 7425927, at *4 (N.D. Cal. Dec. 23, 2016). That is precisely what the State is attempting to do here. Its requested injunctive relief amounts to a "collateral attack on the validity of [a federal agency's] decision," and the State "can only succeed . . . if [it] establish[es] that the agency decision was incorrect." *Bader Farms, Inc. v. Monsanto, Co.*, 2017 WL 633815, at *3 (E.D. Mo. Feb. 16, 2017) (asserting federal question jurisdiction). Montana's motion to remand does not alter this fact.

First, Montana argues that the Court should look only to the face of the complaint to determine whether there is a federal question. This ignores the fact that the State affirmatively asserted a federal question into the case by demanding injunctive relief that would displace the federally mandated regulatory and labeling scheme for prescription medications. Purdue's removal, based on the State's motion as "other paper," was proper under 28 U.S.C. § 1446(b)(3).

Second, the State argues that remand is required under *Merrell Dow Pharm. Inc. v. Thomson*, 478 U.S. 804 (1986), because the FDCA does not provide for a private right of action. But the Supreme Court's subsequent decision in *Grable* expressly rejected an analogous argument, clarifying that the lack of a private right of action does not preclude federal jurisdiction where, as here, Montana's injunctive relief claims cannot be decided without implicating significant federal issues. *See Grable*, 545 U.S. at 318.

Third, the State argues that federal issues are only implicated by Purdue's anticipated preemption defenses. In so arguing, the State conflates the defense of federal preemption and the existence of federal question jurisdiction. Purdue's removal is not based on any anticipated preemption defense. Rather, it is based on the substantial federal questions raised by the extraordinary injunctive relief sought by the State that would require the Court to "second guess" the FDA's decision-making with respect to the approval of Purdue's opioid medications and the content of their FDA-approved labeling. *McKay*, 2016 WL 7425927, at *5.

Finally, the State argues that Purdue's removal is untimely. But the removal was made within 30 days of the State's motion for preliminary injunction, which demonstrated for the first time that the State's injunctive relief claims raised substantial federal questions, making it timely under 28 U.S.C. § 1446(b)(3). In sum, Purdue's removal of this case to federal court is proper, timely, and based on substantial federal questions. The State's remand motion should be denied.

ARGUMENT

I. THE COURT HAS SUBJECT MATTER JURISDICTION BECAUSE THE STATE'S CLAIMS RAISE SIGNIFICANT FEDERAL QUESTIONS

This Court has "federal question" jurisdiction over the State's case pursuant to 21 U.S.C.

§ 1331, because the State's injunctive relief claims raise a federal question "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314. This principle "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.* at 312. As explained below, and in Purdue's Notice of Removal,[1] which is incorporated by reference, the *Grable* test is met here.

A. The Federal Issues Are Substantial and Disputed

The federal questions embedded in the State's injunctive relief claims are substantial because they are not limited to the immediate lawsuit but are instead important "to the federal system as a whole." *McKay*, 2016 WL 7425927, at *5 (internal quotations omitted). Though the State purports to raise only state law claims, the injunctive relief it seeks directly implicates the FDA's decisions to approve Purdue's opioid medications as safe and effective for their indicated uses. As injunctive relief, the State seeks an order requiring that Purdue "[i]mmediately cease" making certain FDA-approved representations about its prescription opioid medications and instead "in ***all*** [future] promotional or educational activity that could reach Montana prescribers or consumers" affirmatively state that:

- Purdue's "opioids are to be tried only after other treatments have failed";
- "[T]here is no evidence that opioids improve pain, function or quality of life long-term";
- "[T]here is no evidence that screening or risk-stratification tools are effective in preventing addiction or limiting other risks of long-term opioid use"; and
- "[P]rescribers should use the lowest effective dosage and should avoid increasing dosage to ≥ 90 MME/day."

Mot. for Prelim. Inj. at 2-3 (emphasis added) (Exh. A). Though the State contends that the

[1] Notice of Removal, *State of Montana v. Purdue Pharma L.P.*, No. 6:18-CV-00033-SEH (D. Mont. Feb. 28, 2018), Dkt. 1.

affirmative representations that it seeks to compel Purdue to make are "derived from" the CDC Guideline, *id*. at 2, the State's demands differ in several material ways. Indeed, the Guideline is just that: a professional recommendation. Montana's attempt to turn it into mandatory requirements necessarily fails. *See, e.g.*, *United States ex rel. Polansky v. Pfizer*, 822 F.3d 613, 618 (2d Cir. 2016) ("[G]uidelines usually provide advice and (unsurprisingly guidance, 'not mandatory limitation.'"). In any event, the State's request for injunctive relief raises the substantial federal question of whether the State may use Montana law to compel Purdue to supplant the warnings and labeling that the FDA has determined to be appropriate with the conflicting standards in the CDC Guideline, when the CDC has no regulatory authority over Purdue or any prescription medication and, in any event, the CDC intended the Guideline only to provide "recommendations," not "prescriptive standards."[2]

Purdue's medications are subject to extensive regulation by the FDA under the FDCA, 21 U.S.C. §§ 301, *et seq.*, and its implementing regulations. 21 C.F.R. §§ 1.1, *et seq*. The purpose of the FDCA is to establish uniform nationwide standards for the regulation of pharmaceutical medications in order to "promote" and "protect the public health by ensuring that . . . human . . . drugs are safe and effective." 21 U.S.C. § 393(b). The FDA must approve any prescription medication before it is marketed or sold, *id*. § 355(a), to ensure that "drugs are safe and effective" for their approved intended uses, *id*. § 393(b)(2)(B). After a prescription medication is approved, it remains subject to continued FDA oversight. 21 C.F.R. §§ 314.80, *et seq*.

Congress has vested the FDA with exclusive regulatory responsibility for "determin[ing] whether a drug is generally recognized as safe and effective." *Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 654 (1973). This includes the exclusive regulatory authority to determine the precise content of prescription drug labeling (*e.g.*, the instructions, warnings, precautions, adverse reaction information provided by manufacturers, and marketing materials), 21 U.S.C. §§ 301 *et seq.*; *id*. § 393(b)(2)(B), and the FDA "retains authority" to approve or reject labeling changes. *Wyeth v.*

[2] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 ("CDC Guideline"), at 2 (Exh. B).

Levine, 555 U.S. 555, 570-71 (2009). If a pharmaceutical manufacturer's statements about its medication are inconsistent with the FDA-approved labeling, the medication may be considered misbranded under federal law. 21 U.S.C. § 352. The penalties for selling a misbranded prescription medication are significant and include civil fines, injunctions and seizures, and in some instances, criminal prosecution. *Id.* §§ 333(b), 334.

The FDA has described FDA-approved labeling as one of the most important written communications made to physicians:

> The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use.[3]

Yet the State seeks to usurp the FDA's exclusive regulatory authority through a prospective court-ordered injunction that would compel Purdue to make affirmative representations about its opioid medications based on the CDC Guideline, which is indisputably different from and, at times, inconsistent with the FDA-approved labeling for Purdue's opioid medications.

For example, the State's injunctive demand requires Purdue to tell healthcare providers that its prescription "opioids are to be tried only after other treatments have failed" (Mot. for Prelim. Inj. at 2 (Exh. A)). But the FDA-approved labeling expressly states that OxyContin may be used where "alternative treatment options . . . would be otherwise inadequate to provide sufficient management of pain."[4] Thus, a rehabilitation or orthopedic physician need not wait to initiate opioid therapy where other therapies would not adequately treat a catastrophic multi-trauma patient's chronic pain. Consequently, by requiring that Purdue affirmatively tell doctors that opioids can ***only*** be prescribed after other non-opioid pain modalities have been tried and

[3] FDA, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922-01, 3934 (Jan 24, 2006).

[4] OxyContin Labeling, at 1 (Exh. C).

failed, the State is directly challenging the FDA's assessment that for some patients suffering from severe pain, opioid analgesics are an appropriate first-line form of relief.

That is not the only conflict. The State also seeks an order that requires Purdue to tell healthcare providers that "there is no evidence that opioids improve pain, function or quality of life long-term" (Mot. for Prelim. Inj. at 2 (Exh. A)), which the State claims is "derived from" the CDC Guideline's assertion that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later [and] [e]xtensive evidence shows the possible harms of opioids."[5] Yet the FDA, Purdue's exclusive regulator, disagrees with the CDC's position. In 2013, the FDA noted that there were numerous studies that suggested that some patients taking opioid medications may continue to experience benefits that would support the use of opioids for more than 90 days.[6] Thus, as the FDA-approved labeling for Purdue's OxyContin instructs physicians, "OxyContin is an opioid agonist indicated for pain severe enough to require daily, around-the-clock, ***long-term*** opioid treatment and for which alternative treatment options are inadequate."[7]

The divergence between FDA-approved labeling and the CDC Guideline is unsurprising: the FDA labeling is meant for an array of healthcare professionals, including primary care clinicians and other pain specialists, treating all types of pain, including acute, chronic, cancer, and non-cancer pain, in all settings, including end-of-life, in the hospital, in hospice, or at home. In contrast, the CDC Guideline has a narrower purpose: "This guideline provides recommendations for the prescribing of opioid pain medication by primary care clinicians for chronic pain (i.e., pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care."[8] Yet the State's injunctive relief claims disregard these important distinctions in intended audiences and seek to

[5] CDC Guideline, at 15 (Exh. B).
[6] Letter from the FDA to PROP at 10 n.40 (Sept. 10, 2013) (Exh. D).
[7] OxyContin Labeling, at 1 (emphasis added) (Exh. C).
[8] CDC Guideline, at 2 (Exh. B).

transform the CDC Guideline into binding regulations that would apply not just to primary care clinicians, but to clinicians treating varying types of pain in varying types of settings.

Insofar as the State's requested relief seeks to dictate what Purdue can and cannot say about its medications "in ***all*** [future] promotional or educational activity," that is an attempt by the State to prospectively regulate Purdue's labeling through a court-ordered injunction. Mot. for Prelim. Inj. at 2 (emphasis added) (Exh. A). This raises substantial federal questions.

In seeking injunctive relief that would compel Purdue to make affirmative representations based on the non-binding CDC Guideline that contradicts the FDA-approved labeling of Purdue's medications, the State attempts to supplant the FDA's regulatory directives about what information Purdue must communicate to doctors about the safety, efficacy, and appropriate prescribing of its medications. Federal questions arise where "the remedies [a party] seek[s] require nothing short of a reassessment, reevaluation and revamping of [a federal agency's earlier determination]" because that is "tantamount to asking the Court to second guess the validity of [the agency's] decision." *McKay*, 2016 WL 7425927, at *4; *Citizens All. to Save Southline v. Montana Rail Link, Inc.*, 672 F. Supp. 1576, 1579 (D. Mont. 1987). Here, the State's claims amount to a "collateral attack on the validity of [a federal agency's] decision," and the State "can only succeed . . . if [it] establish[es] that the agency decision was incorrect." *Bader*, 2017 WL 633815, at *3. "Under these circumstances," the State's claims "present[] a substantial federal question." *Id*.

The facts in *McKay* parallel those here. In *McKay*, plaintiffs sought to enjoin the city and county from using new FAA-approved flight paths for the local airports because plaintiffs claimed the flight paths increased noise and pollution over their properties. 2016 WL 7425927, at *1. Defendants removed on federal question grounds and the court denied plaintiffs' remand motion, finding that their claims implicated substantial federal issues. *Id*. at *3-5. The court reasoned that the requested injunction "require[d] nothing short of a reassessment, reevaluation and revamping of the [FAA's] order" because "[a] request to enjoin the use of the flight paths after the FAA's approval is tantamount to asking the Court to second guess the validity of the FAA's decision," which thus impedes the FAA's authority to approve flight paths. *Id*. at *4

Here, the injunctive relief sought by the State similarly seeks to "second guess the validity" of the FDA's decision. By seeking to enjoin Purdue from marketing its medications consistent with its FDA-approved labeling, a court would be required to "reassess[], reevaluate[] and revamp[]" the FDA's approval of Purdue's labeling, over which FDA has authority. *Id*. The State claims that *McKay* is distinguishable because "the State here does not challenge FDA authority to regulate opioids." State Br. at 10. But in *McKay*, plaintiffs also did not directly challenge the FAA's rulemaking authority. Yet the *McKay* court found that the request to enjoin the flight paths was "tantamount" to challenging the FAA's authority to approve those flight paths. *McKay*, 2016 WL 7425927, at *4. The same is true here. The State's request to enjoin Purdue from marketing its opioid medications consistent with its FDA-approved labeling is "tantamount" to challenging the FDA's authority to approve that labeling.

Likewise, in *Bader*, the plaintiffs, a group of farmers, sued for crop damage resulting from the defendant's sale of genetically engineered seeds without a corresponding less-harmful herbicide. 2017 WL 633815, at *1. The plaintiffs asserted state law claims, including a fraudulent concealment claim based on the defendant's alleged withholding of information from the Animal and Plant Health Inspection Service (APHIS) (the federal agency that regulates seed) in its petition to APHIS to deregulate its genetically engineered seeds. *Id*. at *1-2. The court held that "[d]espite plaintiffs' argument that they are not challenging the agency decision itself, they can only succeed on [the fraudulent concealment] count if they establish that the agency decision was incorrect due to defendant's fraudulent concealment." *Id*. at *3. Because "the outcome of the fraudulent concealment claim necessarily depends on the interpretation and application of the federal regulatory process under APHIS," the claims gave rise to a substantial federal question. *Id*.

The State claims that *Bader* is distinguishable because it is not alleging that "Purdue has defrauded the FDA" (State Br. at 11), but that is irrelevant. The court in *Bader* did not find that *only* fraudulent concealment claims could present a substantial federal question. Instead, it found that the nature of the fraudulent concealment claim was a "collateral attack on the validity of APHIS's decision," which gave rise to the substantial federal question. *Bader*, 2017 WL 633815,

at *3. So, too here, the nature of the State's injunctive relief request which seeks to enjoin Purdue from marketing its medications consistent with its FDA-approved label is a collateral attack on the FDA's decision to approve that labeling. *See also Montana Rail*, 672 F. Supp. at 1579 (requested relief was "clearly" federal because it was within the jurisdiction of a federal agency).

B. Asserting Jurisdiction Maintains the Balance Between Federal and State Judicial Responsibilities

The determination of the substantial and disputed federal issues that lie at the heart of this case would not "disturb[] any congressionally approved balance of federal and state judicial responsibilities" and would not "herald a[n] . . . enormous shift of traditionally state cases into federal courts." *Grable*, 545 U.S. at 314, 319. The State's claims here are not the individual "garden variety" tort actions of the kind that the Supreme Court characterized as leading to a "horde" of state court cases being removed to federal court. *Id.* at 318. Montana is demanding broad prospective injunctive relief that would usurp the FDA's authority to regulate the information provided to physicians and patients about the safety and efficacy of Purdue's opioid medications in ways that are inconsistent with what the FDA has decided is appropriate and required in every other state in the country. In essence, Montana wants to substitute its judgment for the FDA's expertise and congressionally-authorized duty to determine the safety, efficacy, and labeling of opioid medications. The State's attempt to second-guess decisions by the FDA raises federal questions and is subject to federal question jurisdiction. *See Bader*, 2017 WL 633815, at *3; *McKay*, 2016 WL 7425927, at *4. "Under these circumstances," the State's claims "present[] a substantial federal question" for this court to decide. *Bader*, 2017 WL 633815, at *3.

II. THE STATE'S ARGUMENTS FOR REMAND ARE WITHOUT MERIT

A. The Well-Pleaded Complaint Rule Does Not Apply Here Because Montana's Motion for a Preliminary Injunction Raises Multiple Federal Questions.

The State asserts that the well-pleaded complaint rule bars federal jurisdiction because the State pleads only state law claims. State Br. at 4-6. Under the well-pleaded complaint rule, a suit "arises under" federal law "only when the plaintiff's statement of his own cause of action shows

that it is based upon [federal law]." *Louisville & N.R. Co. v. Mottley*, 211 U.S. 149, 152 (1908). The Sixth Circuit, however, recognizes that the "substantial-federal-question doctrine" as articulated in *Grable* is an "exception" to the well-pleaded complaint rule. *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 560 (6th Cir. 2007); *accord Taylor Chevrolet Inc. v. Med. Mut. Servs. LLC*, 306 F. App'x 207, 210 (6th Cir. 2008). Thus, even if only state law claims are alleged, they may nevertheless give rise to federal question jurisdiction if they necessarily raise a substantial federal question. *Mikulski*, 501 F.3d at 568. As discussed herein and in Purdue's removal notice, the federal issues raised by the State's state law claims as made clear in its Motion for Preliminary Injunction raise substantial federal questions. Removal based on the State's motion as an "other paper" was proper pursuant to 28 U.S.C. § 1446(b)(3).

B. Federal Jurisdiction Is Not Precluded by *Merrell Dow*

The State argues that *Merrell Dow Pharm. Inc. v. Thomson*, 478 U.S. 804 (1986), requires remand. This is incorrect. In *Merrell Dow*, plaintiffs alleged that the defendant's prescription medication caused birth defects and brought various state law tort claims, including a negligence claim based on the allegation that the drug was "misbranded" under the FDCA because its labeling did not provide adequate warnings. 478 U.S. at 805-06. The Court held that the plaintiffs' misbranding allegations did not raise a federal question because "the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction." *Id.* at 814.

In sharp contrast, Purdue's assertion of federal jurisdiction does not turn on an allegation as part of a negligence claim that *Purdue* violated an FDCA regulation. Rather, it is predicated on the fact that *Montana* affirmatively seeks to impose court-mandated prospective injunctive relief that would displace the federal regulatory scheme established by the FDCA. That is, the State seeks to use Montana law to require Purdue to tell healthcare providers information about the safety and efficacy of its prescription opioids that is different from what the FDA requires. In so doing, it would also subject Purdue to the risk of prospective federal criminal and civil liability.

In fact, *Merrell Dow* supports jurisdiction in this case. There, the Court specifically considered whether a federal cause of action would "further the underlying purposes of the legislative scheme" as a factor to determining whether a suit raised a significant federal issue. *Id.* at 811. That factor is present here because Congress promulgated the FDCA to ensure uniformity and safety in the approval and labeling of prescription drugs. 21 U.S.C. § 393(b). To accomplish this goal, Congress vested the FDA with the authority to determine the content of prescription drug labels. *See* 21 U.S.C. §§ 301 *et seq*.; *id*. § 393(b). Montana's request for injunctive relief undermines this Congressional intent in two significant ways. First, by seeking to dictate what Purdue can and cannot say about its medications "in ***all*** [future] promotional or educational activity," the State threatens the uniformity of drug advertising because Purdue will be required to communicate one thing to doctors and patients in Montana, and another to doctors and patients in the rest of the country. Mot. for Prelim. Inj. at 2 (emphasis added) (Exh. A). Second, by requesting that Purdue make certain specific communications to doctors and patients about the prescribing and use of its opioid medications in Montana based on Montana's interpretation of the CDC Guideline, the State usurps the FDA's authority to determine the content of prescription drug labeling. This is precisely a situation where federal question jurisdiction would "serve congressional purposes and the federal system" because the court's jurisdiction would be premised on protecting the congressional intent of the FDCA and the regulatory scheme it provides. *Merrell Dow*, 478 U.S. at 814. This is consistent with *Grable*, which endorsed the concept that uniformity in the application of a detailed federal regulatory scheme is, itself, a substantial federal interest that merits federal jurisdiction. 545 U.S. at 312.

The jurisdictional difference between the type of garden variety products liability claims at issue in *Merrell Dow* and Montana's injunctive relief claims are illustrated by *Little v. Purdue Pharma, L.P.*, 227 F. Supp. 2d 838 (S.D. Ohio 2002). There, plaintiff asserted individual personal injury claims, which the district court held did not confer jurisdiction under *Merrell Dow*. *Id*. at 859-60. The court noted, however, that ***if*** the plaintiff had sought "to enjoin [Purdue] from continuing to use its current OxyContin label and [further sought] a court-supervised revamping

of the manufacturing, labeling, and distribution process already sanctioned by the FDA," then the court would be "inclined" to view that as invoking federal question jurisdiction. *Id.* at 859. That is precisely what the State is doing here.

It is true that *Merrell Dow* found significant the fact that the FDCA does not provide plaintiffs with a private right of action; only the FDA can enforce violations of the FDCA. *Merrell Dow*, 478 U.S. at 812. But Montana's attempt to transform this observation into a bright-line rule precluding federal jurisdiction in this case is flawed. State Br. at 6. In fact, the Supreme Court rejected an analogous argument in *Grable*: "*Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the sensitive judgments about congressional intent that § 1331 requires." 545 U.S. at 318 (internal quotations omitted). "If the Supreme Court [in *Grable*] *actually* intended there to be two pathways to federal question jurisdiction (federally-created or 'arising from' federal law), it simply cannot be that the [FDCA's] lack of a federal cause of action would foreclose the second pathway." *Burrell v. Bayer Corp.*, 2017 WL 1032504, at *3 (W.D.N.C. Mar. 17, 2017). Regardless of the existence of a private right of action, the relevant inquiry under *Grable* is "whether federal law is necessarily implicated," *id.* at *2, which it is by the State's request for injunctive relief.

The other cases relied on by Montana—*McGrath ex rel. Montana v. Janssen, LP*, 2009 WL 9136812 (D. Mont. Nov. 30, 2009), and *Montana ex. rel. Fox v. Merck & Co., Inc.*, No. 6:06-CV-00007-DWM (D. Mont. 2015), Dkt. 53—similarly do not support remand here because in neither of those cases did the State request prospective injunctive relief that would require the pharmaceutical company to make affirmative representations regarding its drug based on guidelines other than those mandated by the FDA.[9]

In *Fox*, the defendant argued that the court would be forced to interpret federal Medicaid law in order to resolve the State's claims, but the court held that this was insufficient to give rise

[9] The only injunctive relief sought in those cases was intended to cease the defendants' conduct—it did not require any affirmative action by the defendant going forward. *See* Exh. A to Mot. for Remand, Dkt. 26-2, at 3; *McGrath*, Complaint, Dkt. 1-1, at 38 (D. Mont. Oct. 8, 2009).

to federal question jurisdiction. *See* Exh. A to Mot. for Remand, Dkt. 26-2, at 6, 8-10. Similarly, in *McGrath*, the defendant claimed that the court would be required to interpret federal law in order to determine if it promoted off-label uses of its drugs, as alleged by the State. *McGrath*, 2009 WL 9136812, at *3. The court rejected this argument, finding that the State could prove its claims without resorting to such proof, and even if it did, under *Merrell Dow*, an underlying FDCA violation is insufficient to give rise to federal question jurisdiction. *Id.* at *4. Unlike in *Fox* and *McGrath*, the issue here is not just that the court would have to interpret federal law or find a violation of the FDCA in order to resolve the State's claims. Rather, the court would necessarily have to usurp the FDA's decision to approve Purdue's opioid medications and the labeling.

C. The State Conflates Preemption And Federal Question Jurisdiction

The State argues that the federal issues raised by Purdue are defenses to the State's claims, and therefore are not properly considered in removal. But the State's attempts to repeatedly recast the substantial federal issues raised by its state law claims as potential "defenses," conflate the issues of preemption and federal question jurisdiction. *See* State Br. at 7-8. The basis for this Court's jurisdiction is that the extraordinary injunctive relief sought by the State would require this Court to "second guess the validity" of the FDA's approval of Purdue's opioid medications and its labeling, over which the FDA has exclusive authority. *McKay*, 2016 WL 7425927, at *4. This amounts to a "collateral attack" on the FDA's decision, which raises a substantial federal question, independent of any defense Purdue may raise later. *Id.*; *Bader*, 2017 WL 633815, at *3.

D. Montana's Injunctive Claims Raise Questions Of Law

Montana argues that this is not an appropriate case for *Grable* jurisdiction because there is no "pure question[] of law." State Br. at 9. First, it is not true that "only pure legal issues can trigger substantial federal question jurisdiction," they merely provide the most obvious cases. *Adventure Outdoors, Inc. v. Bloomberg*, 552 F.3d 1290, 1299 (11th Cir. 2008). In any event, such a question is present here where the State's requested injunctive relief would compel Purdue to prospectively make representations about the safety and efficacy of its medications that are

inconsistent with those in their FDA-approved labeling. The question thus is whether the state *can* enjoin Purdue in a manner that would require it to make representations about its medications that are inconsistent with the FDA-approved labeling. That is a question of law because it requires the Court to resolve whether "conduct subject to an extensive federal [] scheme is in fact subject to implicit restraints that are created by state law." *Bd. of Comm'rs of Se. La. Flood Prot. Auth.-E. v. Tenn. Gas Pipeline Co., L.L.C.*, 850 F.3d 714, 724 (5th Cir. 2017), *cert. denied*, 138 S. Ct. 420 (2017). *Grable* jurisdiction exists because a substantial federal issue arises where "[t]he implications for the federal regulatory scheme . . . would be significant." *Id.*[10]

III. PURDUE'S REMOVAL IS TIMELY UNDER 28 U.S.C. § 1446(b)(3)

Purdue's removal was timely because Purdue removed within 30 days from the service of the Motion for Preliminary Injunction—a qualifying "motion" or "other paper" pursuant to 28 U.S.C. § 1446(b)(3)—which revealed, for the first time, the substantial federal questions raised in the State's lawsuit. While removal must generally be filed within 30 days of receiving the initial pleading (*see* 28 U.S.C. § 1446(b)(1)), that "30-day period . . . starts to run only if the initial pleading contains ***solid and unambiguous*** information that the case is removable." *Berera v. Mesa Med. Grp., PLLC*, 779 F.3d 352, 364 (6th Cir. 2015) (emphasis added) (internal quotations omitted). But where, as here, "the initial pleading lacks solid and unambiguous information that the case is removable, the defendant must file the notice of removal 'within 30 days after receipt . . . of a copy of an amended pleading, ***motion***, order or ***other paper***' that contains solid and unambiguous information that the case is removable." *Id.* (quoting 28 U.S.C. § 1446(b)(3))

[10] The State notes that other cases brought by state attorneys generals have been remanded (State's Br. at 11), but none involved the significant federal questions presented here. *New Hampshire v. Purdue Pharma*, 2018 WL 333824, at *1 (D.N.H. Jan. 9, 2018), involved removal as a class action under the Class Action Fairness Act. *Delaware v. Purdue Pharma L.P.*, No. 18-383 (D. Del. Apr. 25, 2018), Dkt. 35 at 1-2, and *New Mexico v. Purdue Pharma L.P.*, No. 1:18-CV-00386-JCH-KBM (D.N.M. June 12, 2018), Dkt. 1, at 3, involved claims against wholesale distributors concerning suspicious orders under the Controlled Substances Act. The issue in *California v. Purdue Pharma L.P.*, 2014 WL 6065907, at *1-2 (C.D. Cal. Nov. 12, 2014), was whether the real parties in interest were counties, as opposed to the State, and thus whether there was diversity jurisdiction. These four cases are thus inapposite and do not help to inform this Court's analysis.

(emphasis added). The "requirement of solid and unambiguous information is akin to ***actual*** notice." *Berera*, 779 F.3d at 364 (emphasis added).

For instance, in *Berera*, defendant removed the case more than 30 days after the initial pleading, but within 30 days of a hearing transcript, which first showed the federal nature of plaintiff's claims. *Id.* at 363-64. Plaintiff moved to remand, arguing that removal was untimely. The district court denied the remand motion, and the Sixth Circuit affirmed because the complaint "failed to solidly and unambiguously inform [defendant] that it could remove the case." *Id.* at 364; *see also Akin v. Ashland Chem. Co.*, 156 F.3d 1030, 1035 (10th Cir. 1998).

So, too, here. On the face of the Complaint, the State purported to bring only state law claims. But it was not until the State moved for a preliminary injunction, that the State provided "solid and unambiguous information that the case is removable," *Berera*, 779 F.3d at 364, or "the first clear notice of removability," *Akin*, 156 F.3d at 1035, by revealing the nature of the injunctive relief it sought. Among other things, the State sought an order requiring Purdue to make four ***specific*** statements about its prescription opioids in any future marketing and promotional activities. The State does not, and cannot, cite to any portions of its Amended Complaint where it sought this type of detailed and prospective injunctive relief. It was only after receipt of this "motion" or "other paper," i.e., the Motion for Preliminary Injunction, that Purdue was provided sufficient notice of the presence of federal questions. Purdue's removal notice was thus timely.

CONCLUSION

For the foregoing reasons, the Court should deny Montana's motion to remand.

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Respectfully submitted,

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